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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,531	01/25/2002	Jeffrey A. Lyon	003/241/SAP	2343

7590

03/25/2003

U. S. Army Medical Research and Materiel Command  
ATTN: MCMR-JA (Ms. Elizabeth Arwine- Patent Atty)  
504 Scott Street  
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EXAMINER

BASKAR, PADMAVATHI

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 03/25/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/057,531

Applicant(s)

LYON ET AL.

Examiner

Padmavathi v Baskar

Art Unit

1645

-- Th MAILING DATE of this communication app ars on the cov r she t with th correspondenc address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-47 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**Election/R strictions**

1. Restriction to one of the following groups of invention is required under 35 U.S.C. 121:

- I. Claims 3-8, 9-14 drawn to a recombinant vector, host cell and method of producing recombinant protein, classified in class 536, subclass 23.7.
- II. Claims 1-2, 19-30 and 35-38 or 46-47 drawn to a recombinant protein MSP-1<sub>42</sub> and a multivalent vaccine classified in class 424, subclass 272.1 and 201.1 respectively.
- III. Claims 15-16 drawn to an antibody classified in class 530, subclass 388.6.
- IV. Claims 17 and 18 drawn to a method for detecting malaria antigen and a kit, classified in class 435, subclass 7.92 and 810 respectively.
- V. Claims 31 and 32 drawn to a method for detecting malaria antibody and a kit classified in class 435, subclass 7.22 and 810 respectively.
- VI. Claims 33 and 34 drawn to a method for in vitro monitoring malaria infection and a kit, classified in class 435, subclass 7.1 and 810 respectively.
- VII. Claims 39-42 or 43-45 drawn to a method for inducing an immune response or protective immune response classified in class 424 subclass 184.1

2. The inventions are distinct, each from the other because of the following reasons:

Group I is directed to DNA which consists of nucleic acids, Groups II is directed to recombinant protein, made of amino acids. Invention III is drawn to an antibody, which is distinct from Inventions I-II since it has an inherent affinity, avidity, and specificity that a DNA or a simple protein is not capable of expressing. These products are different to each other structurally, biochemically and functionally and are drawn to patentably distinct inventions which have materially different physical and chemical properties and structures as represented by their divergent sequences.

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Groups IV-VII are different methods utilizing different products such as protein and antibodies. Thus Inventions IV -VI are patentably different methods using different biological reagents, different method steps that result in different outcome.

3. Invention II is related to invention V/VI/VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein of Group II can be used in immunoaffinity chromatography methods for purifying antibodies and need not be used in the inventions V/VI.

4. Invention III is related to invention IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group III can be used in immunoaffinity chromatography for purifying antigens and need not be used in the inventions VI.

5. Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, the literature and sequence

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searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmavathi v Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on M-F (6:30A.M-4: 00 P.M.) First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

P. Baskar Ph.D.  
3/19/03

  
**LYNETTE R. F. SMITH**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**